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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,563	07/16/2003	Satoshi Kidooka	P23565	7116
7055	7590	08/07/2006	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			PEFFLEY, MICHAEL F	
			ART UNIT	PAPER NUMBER
			3739	
DATE MAILED: 08/07/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/619,563	Applicant(s) KIDOOKA, SATOSHI	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-9 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-9 and 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's amendments and comments, received June 7, 2006, have been fully considered by the examiner. The following is a complete response to the communication of June 7, 2006.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claims 11 and 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claims 1 and 12 have been amended to include the subject matter of dependent claims 11 and 18, respectively, thereby making claims 11 and 18 redundant.

Claim Rejections - 35 USC § 103

Claims 1-3, 5-9 and 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouchi (2002/0123667) in view of Rydell (5,035,696) and further in view of the teaching of Weaver et al (5,536,248).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Ouchi discloses a bipolar treatment tool for an endoscope substantially as set forth in the instant application claims. It includes a flexible insulating tube (102) made of PTFE (col. 3, line 13), an end effector (110,112) attached to the end of the tube and a

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pair of conductive wires (122,124) extending through the tube and coupled to the end effector to provide bipolar energy to the individual jaws. The examiner maintains that the use of any well known insulating material, including a silicone resin, for making the flexible tube is deemed an obvious design consideration for one of ordinary skill in the art. Slater et al also disclose a proximal operating portion (Figure 1) for actuating the pair of conductive wires to operate the end effector . The only features not taught by Ouchi is the provision of two generally circular channels in the insulating tube through which the wires are individually passed. Rather, Ouchi provides a single channel and passes both wires through the single channel, each wire provided with its own individual insulation sheath.

Rydell also discloses a flexible, bipolar tool for an endoscope. In particular, Rydell teaches that the two conductive wires (24,26) may be individually insulated and passed through a lumen in the flexible insulating tube (see Figure 1). Alternatively, Rydell also teaches that the wires may be uninsulated and the flexible insulating sheath may be provided with two channels for housing the wires individually and obviate the need for an insulation coating on the wires (see Figure 5 and col. 5, lines 10-19). The Rydell lumens are semi-circular in shape. The examiner maintains that the use of any shaped lumen in a catheter device would be an obvious design consideration for one of ordinary skill in the art.

In support of this assertion, Weaver et al disclose another flexible electrosurgical tool for an endoscope very much like the Rydell device. In particular, Weaver et al provide lumens in the flexible body for the passage of various instruments and devices,

including electrode leads. Of particular note, Weaver et al teach of the well-known use of variously shaped lumens for providing advantageous characteristics, such as diminished cross sectional area, for the flexible member. Figures 12 and 12a of the Weaver et al device show the use of circular-shaped lumens, and Figures 19-24 show various other configurations including combinations of circular and semi-circular shaped lumens to maximize lumen surface area. In column 10, lines 18-35, Weaver et al specifically disclose that the various alternative lumen shapes are deemed obvious alternatives.

To have provided the Ouchi flexible tube with two channels for providing the individual conductive wires and obviating the need for insulation coatings on the individual wires would have been an obvious alternative arrangement for one of ordinary skill in the art, particularly since Rydell teach that providing two channels in an insulating tube is a known alternative to insulated wires being passed through a single lumen in an insulating tube. To have further provided the two channels as two circular lumens to more fittingly receive the leads would have been an obvious design consideration for one of ordinary skill in the art in view of the Weaver et al patent which teaches that such alternative lumen shapes are generally well known and obvious alternatives.

Claims 1-3, 5-7 and 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slater et al (5,482,054) in view of Rydell (5,035,696) and further in view of the teaching of Weaver et al (5,536,248).

Slater et al discloses a bipolar treatment tool for an endoscope substantially as set forth in the instant application claims. It includes a flexible insulating tube (50,300) made of poly-ethylene (col. 5, line 42), an end effector (18) attached to the end of the tube and a pair of conductive wires (60) extending through the tube and coupled to the end effector to provide bipolar energy to the individual jaws. The examiner maintains that the use of any well known insulating material, including a silicone resin, for making the flexible tube is deemed an obvious design consideration for one of ordinary skill in the art. The only feature not taught by Slater et al is the provision of two generally circular channels in the insulating tube through which the wires are individually passed. Rather, Slater et al provide a single channel and passes both wires through the single channel, each wire provided with its own individual insulation sheath.

Rydell also discloses a flexible, bipolar tool for an endoscope. In particular, Rydell teaches that the two conductive wires (24,26) may be individually insulated and passed through a lumen in the flexible insulating tube (see Figure 1). Alternatively, Rydell also teaches that the wires may be uninsulated and the flexible insulating sheath may be provided with two channels for housing the wires individually and obviate the need for an insulation coating on the wires (see Figure 5 and col. 5, lines 10-19). The Rydell lumens are semi-circular in shape. The examiner maintains that the use of any shaped lumen in a catheter device would be an obvious design consideration for one of ordinary skill in the art.

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provide lumens in the flexible body for the passage of various instruments and devices, including electrode leads. Of particular note, Weaver et al teach of the well-known use of variously shaped lumens for providing advantageous characteristics, such as diminished cross sectional area, for the flexible member. Figures 12 and 12a of the Weaver et al device show the use of circular-shaped lumens, and Figures 19-24 show various other configurations including combinations of circular and semi-circular shaped lumens to maximize lumen surface area. In column 10, lines 18-35, Weaver et al specifically disclose that the various alternative lumen shapes are deemed obvious alternatives.

To have provided the Slater et al flexible tube with two channels for providing the individual conductive wires and obviating the need for insulation coatings on the individual wires would have been an obvious alternative arrangement for one of ordinary skill in the art, particularly since Rydell teach that providing two channels in an insulating tube is a known alternative to insulated wires being passed through a single lumen in an insulating tube. To have further provided the two channels as two circular lumens to more fittingly receive the leads would have been an obvious design consideration for one of ordinary skill in the art in view of the Weaver et al patent which teaches that such alternative lumen shapes are generally well known and obvious alternatives.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slater et al (5,482,054), Rydell (5,035,696) and Weaver et al (5,536,248) as applied to the above claims, and further in view of the teaching of Sutton et al (5,762,613).

Slater et al provides a clevis attachment at the distal end of the device to operate the jaws, but fails to specifically disclose a pair of pins, each pin supporting a separate jaw as recited in claims 8 and 9. Rather, Slater et al provides a single insulative pin (28) upon which both jaws are connected.

Sutton et al disclose a similar device that includes a flexible tubular member (22) with a pair of control wires extending therethrough and connected to jaws (80,81) of an end effector. In particular, Sutton et al teach that the distal end of the device may include a clevis having two separate pins (72,73) with each jaw member connected to a separate pin to allow individual actuation of the jaw members.

To have provided the Slater et al device, as modified by the prior art teachings, with a dual pin clevis construction to allow for the individual actuation of the jaw members would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Sutton et al (5,762,613).

Response to Arguments

Applicant's arguments filed June 7, 2006 have been fully considered but they are not persuasive.

Claim 1 has been amended to recite symmetrically arranged guide channels and that the wires are naked twisted stainless steel wires. It is noted that these limitations were presented in previously rejected claims 4 (now canceled) and 11. Applicant contends that none of the various embodiments of Weaver disclose conductive wires that pass through different circular guide channels (page 7 of applicant's response). The examiner agrees with this characterization of the Weaver reference, however the

examiner maintains that the teaching extracted from Weaver is still applicable to the rejection at hand. As asserted in the previous rejections, Ouchi disclose the general flexible device comprising a flexible tube and an end effector. Rydell clearly teaches that endoscopic bipolar devices may provide the bipolar wires in a single lumen with insulation on the wires (Figure 1) as also taught by Ouchi, or may provide the bipolar wires in an uninsulated condition in separate channels (Figure 5). The examiner maintains this teaching provides clear motivation for one of ordinary skill in the art to provide the Ouchi device with separate lumens as an alternative means to provide the bipolar wires and maintain an electrical separation without the need for an insulated coating on each wire. Weaver, on the other hand, is cited merely to show the various lumen configurations known to those of ordinary skill in the art. Rydell shows semi-circular lumens for the individual wires. The examiner maintains that any lumen shape would be an obvious design consideration, and Weaver clearly shows that it is generally known to use various lumen shapes within a flexible endoscope cross section to provide the necessary number of channels. In as much as the Ouchi and Rydell references would only require at most two channels to carry the two individual wires, there is sufficient room to provide the lumens as two circular lumens as taught by Weaver. Moreover, it is again stressed that applicant's specification fails to provide any particular criticality or unexpected result associated with the particular lumen shape.

Applicant also asserts that Rydell is somewhat distinct from applicant's invention because the wires cannot have insulation. This simply is not true. Figure 1 of Rydell clearly shows an embodiment whereby two wires (24,26) are provided in a single

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lumen, each of the wires having an insulation layer (18) thereon to prevent shorting.

The active portions of the wires have the insulation layer removed as is well-known in the art. Thus, Rydell clearly teaches that two insulated wires in a single lumen (as also taught by Ouchi) is an alternative isolation means to two uninsulated wires located in separate lumens (as set forth in applicant's claims). The examiner maintains that the Rydell teaching provides clear an unambiguous motivation to use either manner of wire delivery to maintain electrical isolation in an endoscopic device.

With regard to the specific lumen size (i.e. applicant's new claims 19 and 20), the examiner maintains that one of ordinary skill in the art would recognize the advantages of properly sizing the lumens the more effectively allow the wires to slide. Applicant's specification fails to show any unexpected result associated with the particular sizing of the lumens, and the examiner maintains that one of ordinary skill in the art would recognize the advantages of properly sizing the lumens to permit the wires to slide easily and without kinking or bending.

Concerning the rejection involving the Slater et al reference, applicant notes that the Slater reference does not disclose a plurality of pins, but rather a single clevis pin. The body of the rejection involving the Slater reference inadvertently included some language from the Ouchi reference, as indicated by the inclusion of the Ouchi name in some portions of the rejection. However, claims 1-7 and 11-18 do not recite the dual pin clevis connection which applicant asserts is missing from the Slater et al reference. Rather, this dual pin connection was recited in the previously submitted claims 8-10,

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and the Sutton et al reference was used to meet the limitations of the use of dual pins as recited in these claims.

With regard to the Sutton reference, applicant contends on page 9 of the response that the examiner has not set forth proper motivation for the proposed combination. The examiner disagrees. There are several well-known actuation connections for forceps devices. Slater discloses the use of a single pin on a clevis to actuate both jaws on a common axis. Sutton teaches that two individual axes may be used to rotatably support the jaws. The examiner maintains that these two arrangements are obvious design expedients to impart movement to forceps jaw members and that they may obviously be interchangeably used. One of ordinary skill in the art would have sufficient motivation to provide any well known actuation connection to operate the jaw members of an endoscopic forceps device based on the particular procedure, the tissue being grasped or personal preference.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

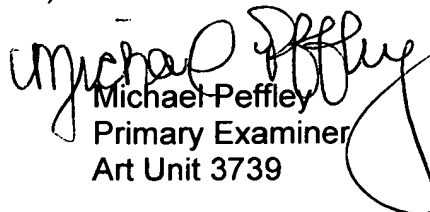
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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Michael Peffley
Primary Examiner
Art Unit 3739

mp
July 25, 2006